**PATIENT INFORMATION LEAFLET**

**Read this leaflet carefully before you take ASTOR.**

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- ASTOR has been prescribed for you or your child personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours or your child's.

**SCHEDULING STATUS**: S4

**PROPRIETARY NAMES (AND DOSAGE FORM):**

ASTOR 10 (film-coated tablets)

ASTOR 20 (film-coated tablets)

ASTOR 40 (film-coated tablets)

ASTOR 80 (film-coated tablets)

**WHAT ASTOR CONTAINS:**

ASTOR 10: Each film-coated tablet contains atorvastatin calcium equivalent to 10 mg atorvastatin.

ASTOR 20: Each film-coated tablet contains atorvastatin calcium equivalent to 20 mg atorvastatin.

ASTOR 40: Each film-coated tablet contains atorvastatin calcium equivalent to 40 mg atorvastatin.

ASTOR 80: Each film-coated tablet contains atorvastatin calcium equivalent to 80 mg atorvastatin.

ASTOR 10, 20, 40 & 80 film-coated tablets also contain the following inactive ingredients: activated attapulgite, Microcelac 100 (consisting of lactose monohydrate and microcrystalline cellulose),

microcrystalline cellulose, pregelatinised starch, hydroxypropyl cellulose, magnesium stearate, silica colloidal anhydrous, and Opadry White (consisting of hypromellose, lactose monohydrate, polyethylene glycol and titanium dioxide).
Contains lactose (milk sugar) – see Important information about some of the ingredients of ASTOR.

**WHAT ASTOR IS USED FOR:**

ASTOR belongs to a group of medicines known as lipid (fat) regulating medicines, also referred to as statins.
ASTOR is used, together with a low fat diet, to reduce your levels of cholesterol and triglycerides (fat in the blood).
It is important to continue with your low fat diet and lifestyle changes while taking ASTOR.

**BEFORE YOU TAKE ASTOR:**

**Do not take ASTOR if you**

- are hypersensitive (allergic) to atorvastatin, any other statin, or any of the ingredients of ASTOR
- have liver problems
- have unexplained abnormal blood tests for liver function
- drink excessive amounts of alcohol
- are a woman able to have children, and are not using reliable contraception
- are pregnant or breast-feeding your baby
- are also taking rifampicin (an antibiotic used for certain types of bacterial infections and tuberculosis) or diltiazem (used to treat high blood pressure and to control chest pain). See also **Taking or using other medicines with ASTOR.**

Do not drink grapefruit juice if you are taking ASTOR. (See **Taking ASTOR with food and drink** below).

**Take special care with ASTOR:**

The presence of other medical problems may affect the use of ASTOR. Talk to your doctor, pharmacist or healthcare professional before taking ASTOR if you:

- have liver or kidney disease
- or your family have a history of any repeated or unexplained muscle aches or pains. Your doctor will refer you for blood tests before, and possibly during, your ASTOR treatment, to predict your risk of muscle related side-effects
- have previously experienced muscle problems while being treated with other statins or other lipid-lowering medicines
- have had a previous stroke with bleeding into the brain
- had an organ transplant and are being treated with immunosuppressants (medicines that suppress activity of the immune system)
- are a heavy drinker of alcohol
- have a severe acute infection
- have low blood pressure (hypotension)
- have uncontrolled seizures
- have major surgery or trauma
- develop jaundice (yellowish discolouration of the whites of the eyes, skin, and mucous membranes caused by deposition of bile salts in these tissues)
- if you have a risk of developing conditions called myasthenia gravis or ocular myasthenia (refer **Side-effects** section under **The following side-effects occur, frequency unknown**)

**Taking ASTOR with food and drink:**

You can take ASTOR tablets with or without food.

ASTOR should not be taken with grapefruit juice, or other grapefruit products in large amounts.

**Pregnancy and Breast-feeding:**

ASTOR should not be used if you are pregnant or breast-feeding.

If you are trying to become pregnant, you should inform your doctor and stop taking ASTOR one month before you plan to conceive.

If you are pregnant or breast-feeding your baby while taking ASTOR, please consult your doctor, pharmacist or other healthcare professional for advice.

**Driving and using machinery:**

ASTOR may cause dizziness, drowsiness or related problems. Make sure you know how you react to ASTOR before you drive or use machines that require you to be alert.

**Important information about some of the ingredients of ASTOR:**

ASTOR contains lactose (milk sugar). If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking ASTOR.

**Taking or using other medicines with ASTOR:**

If you are taking other medicines on a regular basis, including complementary or traditional medicines, the use of ASTOR with these medicines may cause undesirable interactions. Please consult your doctor, pharmacist or other healthcare professional for advice.

Some of the medicines that may interact with ASTOR are:

- medicines used to alter the way your immune system works, e.g. ciclosporin
- certain antibiotics, antiviral or antifungal medicines, e.g. itraconazole, ketoconazole, erythromycin, clarithromycin, HIV-protease inhibitors
- fucidic acid – an antibiotic medicine used for various skin or eye infections
- medicines that prevent blood clotting (e.g. warfarin) – you may find that you bleed more easily
- medicines used to regulate your heart rhythm e.g. digoxin, amiodarone
- other medicines that help lower cholesterol, e.g. cholestyramine, colestipol, fibrates, gemfibrozil or nicotinic acid
- some calcium channel blockers used for chest pain or high blood pressure, e.g. verapamil, diltiazem
- antacids (indigestion products)
- oral contraceptives.

Before you begin using any new medicine (prescription or non-prescription) or if you develop any new medical problem while you are using ASTOR, check with your doctor, nurse or pharmacist.

**HOW TO TAKE ASTOR:**

You must follow a cholesterol-lowering diet before, and during, treatment with ASTOR.

Always take ASTOR exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure. If you have the impression that ASTOR is too strong or too weak, you should talk to your doctor or pharmacist.

Do not share medicines prescribed for you with any other person.

You can take ASTOR tablets with or without food. You should not take ASTOR with grapefruit juice, or other grapefruit products in large amounts.

The usual starting dose is 10 mg ASTOR daily in adults. This may be increased by your doctor until you are taking the amount you need to get the required response.

**If you take more ASTOR than you should:**

You may experience an increase in side-effects and their frequency. In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre. Take this leaflet and any remaining tablets with you, so that the doctor knows what you have taken.

**If you forget to take ASTOR:**

If you miss a dose of ASTOR, take it as soon as you remember. However, if it is almost time for the next dose, skip the missed dose and go back to the regular dosing schedule. Do not take a double dose to make up for forgotten individual doses.

**POSSIBLE SIDE-EFFECTS:**

ASTOR may cause side-effects.

If any of the side-effects become serious, or you notice any side-effects not listed in this leaflet, please tell your doctor or pharmacist.

Stop taking ASTOR and tell your doctor immediately if you experience any of the following side-effects:

- your muscles become weak, painful and tender, especially if you also feel unwell or have a high temperature or if your muscles start cramping. In some cases, this could progress to a serious and potentially life-threatening condition called rhabdomyolysis (a condition of muscle disintegration that can lead to kidney failure)
- loss of appetite, stomach pain, dark-coloured urine, yellow colouring of the skin or the white of the eyes
- allergic reactions (including swelling of the face, eyelids, lips, tongue, throat; difficulty in breathing and swallowing, hives and itching)
- chest pain

If any of the above happens, stop taking ASTOR and tell your doctor immediately or go to the casualty department at your nearest hospital. These are all very serious side-effects. You may need urgent medical attention or hospitalisation.

**The following side-effects occur frequently, consult your doctor if the side-effects persist or become bothersome:**

Trouble in sleeping; dizziness; headache; abnormal skin sensations (as tingling or tickling or itching or burning); a reduced sense of touch or sensation; constipation; diarrhoea; flatulence; heartburn; abdominal or stomach pain and cramps; nausea, indigestion; skin rash; an intense itching sensation; muscle pain; pain in a joint or joints; back pain; fatigue (tiredness); feeling weak, lacking energy or strength.

**The following side-effects occur less frequently:**

If you are pale, feel tired, get frequent infections or your blood takes longer to clot, you may have a lower than normal number of red blood cells, white blood cells or platelets in the blood; low or high blood sugar (ask your doctor how often you should have your blood tested and what tests you need to have done); weight gain; numbness, tingling, or pain, usually in the hands and feet, caused by damage to the peripheral nerves; partial or total loss of memory, forgetfulness, confusion; blurred vision; ringing sound in the ears; loss of hearing; taste disturbances; vomiting; inflammation of the pancreas (you may feel sick, feverish and notice a gradual or sudden pain in the upper abdomen); loss of appetite; inflammation of the liver (you may feel sick, tired, have dark urine, unusually light

coloured stools, yellowing of the skin and whites of the eyes); liver failure (you may for example feel sick, tired, have diarrhoea and a swollen abdomen); decreased sexual ability; excessive development of the breasts in males; loss of hair; hives; muscle disease; muscle weakness, muscle pain, muscle cramps; inflammation of muscle tissue; swelling of the extremities; sinusitis (inflammation of the nasal sinus membranes), pharyngitis (sore, inflamed throat); feeling of general discomfort or uneasiness, increases in blood sugar levels.

**The following side-effects occur, frequency unknown:**

A condition known as myasthenia gravis may occur (frequency unknown). Myasthenia gravis symptoms include weakness of the eye muscles, drooping of one or both eyelids, blurred or double vision, changes in facial expressions, difficulty swallowing, shortness of breath, impaired speech-weakness in the arms, hands, fingers, legs, and neck,.

A condition known as ocular myasthenia may occur (frequency unknown). The symptoms of ocular myasthenia gravis include double vision (seeing two images instead of one), trouble focusing, and drooping eyelids.

Not all side-effects reported for ASTOR are included in this leaflet. Should your general health worsen while taking ASTOR, please consult your doctor, pharmacist or other healthcare professional for advice.

If you notice any side-effects not mentioned in this leaflet, please inform your doctor or pharmacist.

**STORING AND DISPOSING OF ASTOR:**

Store in the original packaging (in the carton) at or below 25 °C.

Do not store your medicine in the bathroom.

Do not use ASTOR after the expiry date printed on the label, container or blister.

Return any expired or unused medicine to your pharmacist for safe disposal. Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

STORE ALL MEDICINES OUT OF THE REACH AND SIGHT OF CHILDREN.

**PRESENTATION OF ASTOR:**

ASTOR film-coated tablets are packed in packs of 28 (4 blisters of 7 film-coated tablets) or 30 (3 blisters of 10 film-coated tablets) in Aluminium/ Aluminium blisters strips in a cardboard carton.

*Not all pack sizes are necessarily marketed.*

**IDENTIFICATION OF ASTOR:**

ASTOR 10: White oval biconvex film-coated tablets, approximately 10,1 x 5,6 mm and 3,7 mm in thickness.

ASTOR 20: White oval biconvex film-coated tablets with a non-functional break line on one side, approximately 12,7 x 6,7 mm and 4,6 mm in thickness.

ASTOR 40: White oblong biconvex film-coated tablets, approximately 19,4 x 7,8 mm and 4,7 mm in thickness.

ASTOR 80: White oblong biconvex film-coated tablets with a non-functional break line on one side, approximately 22,8 x 10,9 mm and 5,7 mm in thickness.

**REGISTRATION NUMBERS:**

ASTOR 10: 44/7.5/1054

ASTOR 20: 44/7.5/1055

ASTOR 40: 44/7.5/1056

ASTOR 80: 44/7.5/1057

**NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATES OF REGISTRATION:**

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**DATE OF PUBLICATION OF THIS PATIENT INFORMATION LEAFLET:**

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